NDA 21-700 AVANDARYL® (rosiglitazone maleate and glimepiride) Tablets

PROPOSED RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of the REMS is to communicate the risks of AVANDARYL.

II. REMS ELEMENTS

A. Medication Guide

A Medication Guide will be dispensed with each AVANDARYL prescription. Because AVANDARYL is a chronic-use medication, it is packaged in a bottle containing a month's worth of therapy, representing a unit of use. The Medication Guide is attached to the side of the bottle. Each Medication Guide is barcode scanned to ensure that the correct version is being used and that the component is available to accompany the bottle.

Because the Medication Guide is included as part of the primary package for AVANDARYL, GSK has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

B. Communication Plan

The REMS for AVANDARYL does not include a Communication Plan.

C. Elements to Assure Safe Use

The REMS for AVANDARYL does not include elements to assure safe use.

D. Implementation System

Because the REMS for AVANDARYL does not include elements to assure safe use, an implementation system is not required.

III. Assessment of REMS

The Timetable for Assessments is as follows:

1st FDAAA assessment: April 2010 (18 months from approval)
2nd FDAAA assessment: October 2011 (3 years from approval)
3rd FDAAA assessment: October 2015 (7 years from approval)

GSK will submit the assessments within 60 days of the close of the intervals as noted above.